"Special 510(k): Device Modification"
AngioDynamics, Inc. NeverTouch II 400µm Fiber and VenaCure Procedure Kit

General Information:

ANGIODYNAMICS, Inc. intends to introduce the following device into commercial distribution:

a)	**Trade Name:**	AngioDynamics, Inc. NeverTouch II 400µm Fiber and VenaCure Procedure Kit
b)	**Legally Marketed Device:**	AngioDynamics, Inc. NeverTouch 600µm Fiber and VenaCure Procedure Kit
	510(k) Number:	K071959
b)	**Common Name:**	Greater Saphenous Vein Procedure Kit
c)	**Classification Name:**	Laser Instrument, Surgical Powered
d)	**Established Registration Number:**	1319211
e)	**Manufacturing Site Address:**	ANGIODYNAMICS, Inc. 603 Queensbury Avenue Queensbury, New York 12804
f)	**Sterilization Site Address:**	Sterigenics / IBA / Griffith Microscience 27 Park Rd. Glens Falls, NY 12801
g)	**Sterilizer Establishment Registration Number**	13196189
h)	**Classification:**	Accessories to Laser Instrument, Surgical Instruments Product Code: GEX 21 CFR 878.4810

JAN 23 2008

i) **Device Equivalence:**

This product is substantially equivalent to the following device:

- AngioDynamics, Inc. NeverTouch 600µm Fiber VenaCure Procedure Kit, K071959
- CoolTouch Laser System, K040921

This device does not present additional risks to patients or different considerations regarding safety and effectiveness than those presented by the predicate devices.

j) **Performance Standards:** None Established

k) **ANGIODYNAMICS® Contact Information:**

Name: Teri Juckett, Regulatory Affairs Manager

Address: 603 Queensbury Avenue
Queensbury, New York 12804

Phone: (518) 798-1215 extension 1142

Fax: (518) 798-3625

l) **Payment Identification Number** MD6033627-956733

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 23 2008

AngioDynamics, Inc.
% Ms. Teri Juckett
Regulatory Affairs Manager
603 Queensbury Avenue
Queensbury, New York 12804

Re: K073464
Trade/Device Name: AngioDynamics, Inc. NeverTouch II 400pm Fiber
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: December 28, 2007
Received: December 31, 2007

Dear Ms. Juckett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Application: Special 510(k): Device Modification

Device Name: AngioDynamics, Inc. NeverTouch II 400µm Fiber

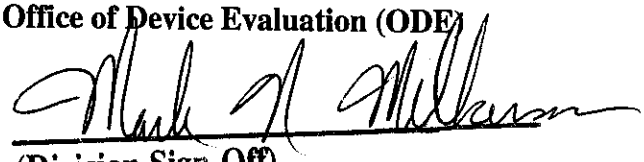
Indications for Use:

The AngioDynamics, Inc. NeverTouch II Fiber is indicated for endovascular coagulation of the great saphenous vein in patients with superficial vein reflux, for the treatment of varicose veins and varicosities associated with superficial reflux of the great saphenous vein, and for the treatment of incompetence and reflux of superficial veins of the lower extremity.

Prescription Use ____X_____ **OR** **Over-the-Counter Use** _____
(Per 21 CFR 801.109)

Please do not write below this line - continue on another page if needed

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K073464